



Patent  
030727.0044.CPA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Duft, *et al.*

Serial No.: 09/445,517

Filed: June 5, 1998

For: METHOD FOR TREATING OBESITY

Group Art Unit: 1645

Examiner: Devi, S.

TRANSMITTAL LETTER

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed are the following documents:

- Transmittal Letter
- Information Disclosure Statement
- PTO Form 1449
- Copies of 76 cited references
- Return Postcard

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(37 CFR §1.8 a)

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No fee is believed due in connection with this transmittal. However, if any fee is due, kindly charge the appropriate amount to Deposit Account No. 50-1273.

Respectfully submitted,

BROBECK, PHLEGER & HARRISON, LLP

Dated: \_\_\_\_\_

6/04/01

By: \_\_\_\_\_

Edward O. Kreusser  
Reg. No. 38,523

Brobeck, Phleger & Harrison LLP  
12390 El Camino Real  
San Diego, CA 92130  
Phone (858) 720-2500  
Fax (858) 720-2555



#8

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the Applicants' duty under 37 CFR 1.56, Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO-1449. Applicants respectfully request that the documents be made of record in the above-referenced application. Copies of the documents are enclosed for the convenience of the Examiner.

The items identified in this Information Disclosure Statement may or may not be "material" pursuant to 37 CFR 1.56 and the submission thereof by Applicants shall not be construed as an

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admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR 1.97(h)), or even qualifies as "prior art" under 35 U.S.C. § 102 with respect to this invention unless specifically designated by Applicants as such.

The filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information, as defined in 37 CFR 1.56, exists.

This Information Disclosure Statement is being submitted under 37 CFR 1.97(c) (2).  
Enclosed is a check in the amount of \$180.00 to cover the fee pursuant to 37 CFR 1.17(p). The Commissioner is authorized to charge any additional fee required by this submission or to credit any over payment to counsel's Deposit Account No. 50-1273.


Respectfully submitted,

BROBECK, PHLEGER & HARRISON, LLP

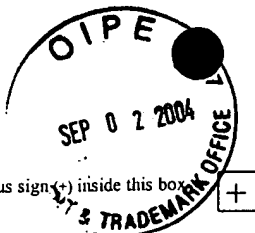
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12390 El Camino Real  
San Diego, CA 92130  
Phone (858) 720-2500  
Fax (858) 720-2555



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

Application Number	09/445,517
Filing Date	December 6, 1999
First Named Inventor	Duft, et al.
Group Art Unit	1645
Examiner Name	S Devi, Ph.D.
Attorney Docket Number	030639.0044 CPA

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of

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### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MMDDYYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,367,052		Cooper, G.J.S.	11/22/94	
	AB	5,175,145		Cooper, G.J.S.	12/29/92	
	AC	5,124,314		Cooper, G.J.S.	6/23/92	
	AD	5,266,561		Cooper, G.J.S.	11/30/93	
	AE	5,264,372		Beaumont, K.	11/23/93	
	AF	5,376,638		Young, A.A.	12/27/94	
	AG	5,656,590		Rink, T.J.	8/12/97	
	AH	5,234,906		Young, A.	8/10/93	
	AI	5,686,411		Gaeta	11/11/97	
	AJ	5,264,372		Beaumont	11/23/93	
	AK	5,280,014		Cooper, G.J.S.	1/18/94	
	AL	5,364,841		Garth, J.S.	11/15/94	
	AM	5,739,106		Rink, T.J.	4/14/98	

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	AN	WO	9640220	Kolterman	12/19/96		
	AO	WO	9220367	Rink	11/26/92		

### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AP	ALAM <i>et al.</i> , "Selective Angatonism Of Calcitonin-Induced Osteoclastic Quiescence (Q Effect) By Human Calcitonin Gene-Related Peptide-(Val <sup>18</sup> Phe <sup>37</sup> )," <i>Biochem. Biophys.</i>	

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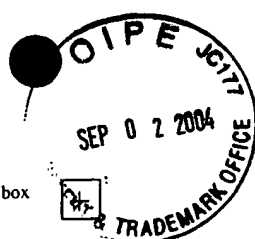
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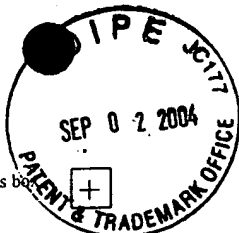
	<u>Res. Commun.</u> , 179(1):134-139 (1991)	
AQ	ARNELO, U., et al, "Chronic infusion of islet amyloid polypeptide causes anorexia in rats," <u>Regulatory Integrative and Comparative Physiology</u> 40(6):R1654-R1659 (1996)	
AR	BEAUMONT et al., "Regulation of muscle glycogen metabolism by CGRP and amylin: CGRP receptors not involved," <u>Br. J. Pharmacol.</u> , 115(5):713-715, 1995	
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AU	BRAY, G.A. "Treatment of Obesity: A Nutrient Balance/Nutrient Partition Approach," <u>Nutrition Reviews</u> 49:33-45 (1991)	
AV	BRODERICK et al., "Human and Rat Amylin have no Effects on Insulin Secretion in Isolated Rat Pancreatic Islets," <u>Biochem. Biophys. Res. Commun.</u> , 177:932-938, 1991	
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AX	CHANCE et al., "Anorexia following the intrahypothalamic administration of amylin," <u>Brain Res.</u> , 539:352-354, 1991	
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BB	COOPER et al., "Amylin and the amylin gene: structure, function and relationship to islet amyloid and to diabetes mellitus," <u>Biochem. Biophys. Acta.</u> , 1014:247-258, 1989	
BC	COOPER et al., "The Amylin Superfamily: A Novel Grouping of Biologically Active Polypeptides Related to the Insulin A-Chain," <u>Prog. Growth Factor Research</u> , 1:99-105, 1989	
BD	COOPER et al., "Amylin found in amyloid deposits in human type 2 diabetes mellitus may be a hormone that regulated glycogen metabolism in skeletal muscle," <u>Proc. Natl. Acad. Sci., USA</u> , 85:7763-7766, 1988	
BE	COOPER et al., "Purification and characterization of a peptide from amyloid-rich pancreases of type 2 diabetic patients," <u>Proc. Natl. Acad. Sci., USA</u> , 84:8628-8632, 1987	

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Group Art Unit	1645
Examiner Name	S Devi, Ph.D.
Attorney Docket Number	030639.0044 CPA

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BF	COOPER et al., "Amylin found in amyloid deposits in human type 2 diabetes mellitus may be a hormone that regulated glycogen metabolism in skeletal muscle," <u>Proc. Natl. Acad. Sci., USA</u> , 85:7763-7766, 1988 (duplicate)
BG	DEEMS et al., "Amylin or CGRP (8-37) Fragments Reverse Amylin-induced Inhibition of <sup>14</sup> C-Glycogen Accumulation," <u>Biochem. Biophys. Res. Commun.</u> , 181(1):116-120, 1991
BH	FOLLETT et al., "Effect of Amylin on Insulin receptor Kinase Activity In Vivo in the Rat," <u>Clinical Research</u> , 39(1):39A (1991)
BI	GAETA and RINK, "Amylin: A new hormone as a therapeutic target in diabetes mellitus and other metabolic diseases," <u>Med. Chem. Res.</u> , 3:483-490, 1994
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BK	GARDINER et al., "Antagonistic Effect of Human -Calcitonin Gene-Related Peptide (8-37) on Regional Hemodynamic Actions of Rat Islet Amyloid Polypeptide in Conscious Long-Evans Rats," <u>Diabetes</u> , 40:948-951, 1991
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BM	GEDULIN et al., "Endogenous Amylin and Gastric Emptying in Rats: Comparison with GLP-1 and CCK-8," <u>Diabetologia</u> , 38 (suppl 1): A244 (1995)
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BO	HUANG et al., "Hyperamylinemia, Hyperinsulinemia, and Insulin Resistance in Genetically Obese LA/N-cp Rats," <u>Hypertension</u> , 19:I-101-I-109, 1991
BP	JUNG and CHONG, "The Management of Obesity," <u>Clinical Endocrinology</u> 35:11-20 (1991)
BQ	KODA et al., "Amylin concentrations and glucose control," <u>The Lancet</u> , 339:1179-1180, 1992
BR	KOLTERMAN et al. "Effect of 14 days' subcutaneous administration of the human amylin analogue, pramlintide (AC137), on an intravenous insuling hallenge and response to a standard liquid meal in patients with IDDM," <u>Diabetologia</u> , 39:492-299, 1996.
BS	KOLTERMAN, "Amylin and glycaemic regulation: A possible role for the human amylin analogue pramlintide," <u>Diabetic Med</u> 14(Supp 2):S35-S38 (1997)
BT	KOOPMANS et al., "Amylin-induced in vivo insulin resistance in conscious rats: the liver is more sensitive to amylin than peripheral tissues," <u>Diabetologia</u> , 34:218-224, 1991
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		resistance to insulin in skeletal muscle <i>in vitro</i> ," <u>Nature</u> , 335:632-635, 1988	
BV		LUDVIK, et al, "Amylin: history and overview," <u>Diabet. Med.</u> 14(Supp 2)(1997)(see abstract)	
BW		LUPIEN et al., "No measureable effect of amylin in lipolysis in either white or brown isolated adipocytes from rats," <u>Diab. Nutr. Metab.</u> , 6(1):13-18, 1993	
BX		LUTZ, et al, "Reduction of food intake in rats by intraperitoneal injection of low doses of amylin," <u>Physiol. Behav.</u> 55(5): 891-895 (1994)	
BY		MACDONALD et al., "Infusion of the Human Amylin Analogue, AC137 Delays gastric Emptying in Men with IDDM," <u>Diabetologia</u> 38 (suppl 1): A32 (abstract 118) 1995	
BZ		MOLINA et al., "Induction of Insulin Resistance In Vivo by Amylin and Calcitonin Gene-Related Peptide," <u>Diabetes</u> , 39:260-265, 1990	
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CB		MORLEY, et al, "Amylin decreases food intake in mice," <u>Peptides</u> 12(4):865-869 (1991)	
CC		MORLEY, et al, "Effects of amylin on appetite regulation and memory," <u>Can. J. Physiol. Pharmacol.</u> 73(7):1042-1046 (1995)	
CD		MORLEY, et al, "Modulation of food intake by peripherally administered amylin," <u>Am. J. Physiol</u> 267(1)(Pt 2):R178-R184 (1994)	
CE		MOYSES, et al "Modulation of gastric emptying as a therapeutic approach to glycaemic control," <u>Diabetic Medicine</u> 13(5)(Supp 1): S34-S38 (1996)	
CF		NOWAK et al. "Accelerated gastric emptying in diabetic rodents: Effect of insulin treatment and pancreas transplantation," <u>J. Lab. Clin. Med.</u> , 123(1):110-6, 1994	
CG		PITTNER et al., "Amylin and epinephrine have no direct effect on glucose transport in isolated rat soleus muscle," <u>FEBS Letts.</u> , 365(1):98-100, 1995	
CH		PITTNER et al., "Molecular Physiology of Amylin," <u>J. Cell. Biochem.</u> , 55S:19-28, 1994	
CI		PLOURDE et al., "CGRP 8-27 Blocks the Inhibition of Gastric Emptying Induced by Intravenous Injection of -CGRP in Rats," <u>Life Sci.</u> 52:857-862, 1993	
CJ		RINK et al., " Structure and biology of amylin," <u>Trends In Pharmaceutical Sciences (TIPS)</u> , 14:113-118, 1993	
CK		RODEN et al., "Effect of islet amyloid polypeptide on hepatic insulin resistnace and glucose production in the isolated perfused rat liver," <u>Diabetologia</u> , 35:116-120, 1992	
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CM		STEPHENS et al., "Presence of Liver CGRP/Amylin Receptors in Only Nonparenchymal Cells and Absence of Direct Regulation of Rat Liver Glucose Metabolism by	

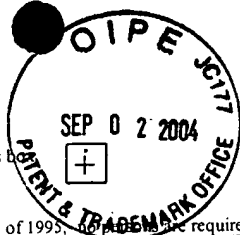
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		CGRP/Amylin," <u>Diabetes</u> , 40:395-400, 1991	
CN		THOMPSON, R.G., et al, "Effects of Pramlintide, an Analog of Human Amylin, on Plasma Glucose Profiles in Patients with IDDM," <u>Diabetes</u> 46:632-636 (1997)	
CO		WANG et al., " <sup>8-37</sup> h-CGRP antagonizes actions of amylin on carbohydrate metabolism in vitro and in vivo," <u>FEBS Letters</u> , 291(2):195-198, 1991	
CP		WEISER, et al, "The pharmacologic approach to the treatment of obesity," <u>J Clin. Pharmacol.</u> 37(6):453-473 (1997)	
CQ		YOUNG et al., "Amylin and insulin in rat soleus muscle: dose responses for cosecreted noncompetitive antagonists," <u>Am. J. Phys.</u> , 263(2):E274-E281, 1992	
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CS		YOUNG et al., "Gastric emptying is accelerated in diabetic BB rats and is slowed by subcutaneous injections of amylin," <u>Diabetologia</u> , 38(6):642-648, 1995	
CT		YOUNG, A.A., et al, "Preclinical Pharmacology of Pramlintide in the Rat: Comparisons with Human and Rat Amylin," <u>Drug Development Research</u> 37: 231-248 (1996)	
CU		YOUNG et al., "Amylin activates glycogen phosphorylase in the isolated soleus muscle of the rat," <u>FEBS Letters</u> , 281(1,2):149-151, 1991	
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CX		ZHU et al., "Amylin Increases Cyclic Amp Formation in L6 Myocytes through Calcitonin Gene-Related Peptide Receptors," <u>Biochem Biophys. Res. Commun.</u> , 177(2):771-776, 1991	

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